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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
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EXAMINER	
BADR, HAMID R	

ART UNIT	PAPER NUMBER
1794	

MAIL DATE	DELIVERY MODE
05/08/2009	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/530,813	ODA ET AL.	
	Examiner	Art Unit	
	HAMID R. BADR	1794	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *05 February 2009*.

2a)☒ This action is **FINAL**. 2b)☐ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *2,5-10 and 12-16* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *2, 5-10, 12-16* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☐ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

DETAILED ACTION

Applicants' amendment filed on 02/05/2009 is acknowledged.

Claims 1, 5-10, 12-16 are being considered on the merits.

Claim Rejections - 35 USC § 102

1. The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

> A person shall be entitled to a patent unless –
>
> (b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claim 2 is rejected under 35 U.S.C. 102(b) as being anticipated by Draaisma et al. (US 2002/0182301; hereinafter R1).

3. R1 discloses a fermented milk product having angiotensin converting enzyme I (ACE) inhibitory activity. The milk product is produced from milk fermented with Lactobacillus *delbrueckii subsp. lactis* (Abstract)

4. R1 claims fermented milk products wherein the milk product is milk, a milk type drink, yoghurt, dairy spread or cheese.

5. Given that R1 discloses ACE inhibitory activity of at least 35 U/ml (abstract), it is clear that the amount disclosed by R1 overlaps that presently claimed.

6. R1 further discloses that dairy type products such as dairy spreads and cream cheese can contain the ACE inhibitory activity. Given that cheese spreads and cream cheese are prepared from raw materials comprising natural cheese containing ACE

inhibitory activity, the inhibitory activity per gram of product will be the presently claimed levels of such activity.

7. Claims 2, 5-10, 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by Henson (WO 97/18718; hereinafter R2).

8. R2 discloses a method for producing a reduced sodium processed cheese from a natural cheese. (Abstract)

9. R2 teaches making reduced sodium processed cheese by a combination of phosphate salts where a natural cheese alone or in combination with other cheeses can be used to achieve the desired flavor profile of the processed cheese. Such natural cheeses can be salted, unsalted or lightly salted alone or in combination (page 4, lines 5-10). A medium aged, natural cheese such as regular cheddar, typically 4-6 months old or unsalted or lightly salted cheddar of up to 3 months old can be used to make the processed cheese (page 6, lines 16-22).

10. R2 discloses that the processed cheese has a salt content of 550-950 mg Na/100g (page 3, lines 22-24). R2 gives an example of a processed cheese product having 800 mg sodium per 100 g of product (page 9, Example 1). R2 discloses the method for producing a reduced sodium cheese containing 830 mg sodium per 100 g product in which dipotassium phosphate is used at 0.5% (page 10, example 2). Given that dipotassium phosphate (anhydrous salt) has a molecular weight of 174, 0.5% of this salt provides about 224 mg of potassium per 100 g of cheese. To produce cheese at lower potassium content, the DKP maybe reduced to half of the amount to result in

about 100 mg potassium per 100 g of cheese. R2 discloses using the salts within the 0.25-0.75% range to avoid bitterness resulting from the use of potassium phosphate salts (page 5, lines 7-9).

11. R2 discloses processing natural cheese alone or in combination with other cheeses, as presently claimed, and R2 also teaches using aged cheese. Since natural aged cheese inherently has ACE inhibitory activity of 420 U/g or more as presently claimed, the processed cheese would inherently have ACE inhibitory activity of 350 U/g or more as presently claimed.

12. Claims 2, 5-10, 12-16 are rejected under 35 U.S.C. 102(b) as being anticipated by JP 2003-033136 (Machine translation, hereinafter R3).

13. R3 discloses a processed cheese with a sodium content of 800 mg /100 g or less and a potassium content of 100 mg/100g or more. R5 discloses the process for making the reduced sodium cheese using potassium pyrophosphate, potassium phosphate and potassium citrate (Abstract).

14. R3 discloses that any natural cheese used for the manufacture of processed cheese may be used including cheddar, camembert, blue cheese, emmental, edam , cream cheese, etc. A combination of one or more sources as presently claimed may be used [006].

15. R3 teaches using various potassium phosphates and potassium citrate to reduce the sodium content of natural cheeses in making a processed cheese. [007].

16. R3 uses cheddar cheese (a New Zealand product) and Gouda cheese for the production of reduced sodium processed cheese. (page 3, work example 1). Given that R3 discloses processing natural cheese as presently claimed as well as discloses using cheese identical to that used in the present invention, i.e. New Zealand cheddar, it is clear that the natural cheese, used as raw material, would inherently have ACE inhibitory activity of 420 U/g or more as presently claimed and the processed cheese would inherently have ACE inhibitory activity of 350 U/g or more as presently claimed.

Response to Arguments

Applicants' arguments have been thoroughly reviewed. These arguments are not deemed persuasive for the following reasons.

1. Applicants argue that the methods and the products as presently claimed have certain advantages and such methods and products may be uniformly commercialized.

a. It should be realized that the methods and products disclosed by the cited references have the same advantages and those methods and products are meant for commercialization as well.

2. Applicants argue that Draaisma et al. (R1) discloses a cheese having an inhibitory activity of at least 35% which cannot have 350 activity units/gram or more as presently claimed.

a. Applicants' attention is drawn to the quantitative value of 35 U/ml, which is reported as the minimum inhibitory activity (in units/ml) This is a general activity per unit

volume of any fermented product. In a concentrated product such as cheese, the inhibitory activity will be equal to the levels as presently claimed.

On the other hand, The inhibitory effect of at least 35%, as claimed by R3, relates to the proteolytic activity of certain organisms producing defined peptides and is disclosed generally for fermented milk products. This is the minimum inhibitory effect by specific peptides. A concentrated fermented product such as cheese will inherently contain the inhibitory levels as presently claimed.

In response to the argument that R1 fails to show how to obtain a cheese, applicants are referred to paragraph [0027] where dairy spreads and cream cheese are given as examples of dairy products which can contain ACE inhibitory action.

3. Applicants argue that adding the fermented product of R1 to angiotensin converting enzyme, will inhibit 35% of the activity, regardless of the amount of the fermented dairy product used.

a. Percent inhibition as reported by R1 is the calculated inhibition under assay conditions. This inhibition is being defined for certain concentrations of ACE as well as the inhibitor. Please see paragraphs [0060 -0067].

4. Applicants argue that Henson (R2) only describes processed cheese with decreased sodium and potassium and fails to describe a processed cheese having ACE inhibitory activity as presently claimed.

a. Henson discloses the method of processing cheese using salted, unsalted or lightly salted cheeses alone or in combination. Such cheeses as disclosed by Henson can be aged. Aged cheese will inherently contain high concentrations of ACE inhibitory

peptides. Therefore, while low sodium processed cheese having potassium is disclosed by Hanson, the ACE inhibitory activity will be inherent in the products.

5. Applicants argue that JP-2003-033136 (R3) discloses processed cheese with decreased sodium and potassium and it fails to describe a processed cheese having ACE inhibitory activity.

a. The preparation of processed cheese using a single natural cheese or a combination of cheeses is disclose by R3. Among the cheeses disclosed cheddar cheese, camembert cheese, blue cheese, emmental cheese are disclosed. These cheese types inherently contain high levels of short peptides capable of inhibiting ACE. When such cheese types are used as raw materials for the processed cheese products, the ACE inhibitory activity of the product be the levels as presently claimed.

Conclusion

1. **THIS ACTION IS MADE FINAL.** Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the mailing date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to HAMID R. BADR whose telephone number is (571)270-3455. The examiner can normally be reached on M-F, 8:00-5:00.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Keith Hendricks can be reached on (571) 272-1401. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Hamid R Badr
Examiner
Art Unit 1794

/KEITH D. HENDRICKS/

Supervisory Patent Examiner, Art Unit 1794